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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,019	11/21/2001	Peter T. Pugliese	Prov.#1-3	9491

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/10/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/989,019	PUGLIESE, PETER T.
	Examiner	Art Unit
	San-ming Hui	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 May, 2002, 07 June 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

The amendments filed May 10, 2002 in attempt to correct the typographical error have been considered and found persuasive to withdraw the outstanding objections to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the oligomeric proanthrocyandins" in line 1. There is insufficient antecedent basis for this limitation in the claim. Please note that the expression recited in claim 11 is not a typographical error. There is no recitation of "the oligomeric proanthrocyandins" in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over
① Soudant et al. (US Patent 5,436,230), Majeed et al. (US Patent 5,804,596), Lotte (JP7-

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61927), Kuppusamy et al. (Biochem. Pharmacol. 1992; 44(7):1307-1315), Sekiya (US Patent 5,776,906), and Koulbanis (US Patent 4,288,433) in view of De Simone (WO 98/01128) and Gennaro (Remington's Pharmaceutical Science, 18th ed., 1990, page 1305 and 1307).

Soudant et al. teaches a topical emulsion composition containing lipolytic agents such as caffeine and carnitine (See col. 2, line 25-38; also claims 21, 26, and 27). Soudant et al. also teaches the composition contains surfactant and a solubilizing agent (See col. 3, line 45 – col. 4, line16). Soudant et al. also teaches a method of slimming the body by topically applying the said emulsion composition onto the skin (See claim 11).

Majeed et al. teaches forskohlin is useful in a method of promoting lean body mass and promoting weight loss (See the abstract). Majeed et al. also teaches the amount of forskohlin to be 1 – 40% of the composition (See the abstract).

Lotte teaches quercetin is useful for prevention and therapy of obesity (See the abstract).

Kuppusamy et al. teaches that both fisetin and quercetin are useful as a lipolytic agents because of the similar structure of both agents (See the abstract).

Sekiya teaches genistein is useful in a method of promoting fat degradation (See claims 4-6).

Koulbanis teaches theophylline in the amount of 0.1 to 5% of the composition is useful as a slimming or anti-cellulite action (See col. 1, line 10-14; also col. 2, line 7-66; and claims 1-3).

The references do not expressly teach that the employment of all the actives together in one composition or method. The references do not expressly teach the employment of the up to about 5% of quercetin, up to about 5% of fisetin, up to about 5% of genistein, up to about 2% of coleus extract, or up to about 1.5% of L-acetyl carnitine into the composition. The references do not expressly teach that the employment of natural gum such as xanthan gum and carrageenan. The references do not expressly teach that the employment of gelling agents such as methoxycellulose, ethoxycellulose, carboxycellulose, acyanacrylate, polyvinylpyrrolidone, or chitosan.

^G
De Simone teaches L-acetyl carnitine is useful in a method of treating obesity (See claims 2 and 4).

^H
Gennaro teaches that methylcellulose and carrageenan are well known to be useful as a gelling agent (See page 1305, col. 2 and 1307, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ all the actives together in one composition or method. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ up to about 5% of quercetin, up to about 5% of fisetin, up to about 5% of genistein, up to about 2% of coleus extract, or up to about 1.5% of L-acetyl carnitine into the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ natural gum such as xanthan gum and carrageenan and gelling agents such as methoxycellulose, ethoxycellulose, carboxycellulose, acyanacrylate, polyvinylpyrrolidone, or chitosan into the topical emulsion composition.

One of ordinary skill in the art would have been motivated to employ all the actives together, in the weight ratio herein, in one composition or method because all the actives herein are known to be useful as a fat degradation promoting agents or lipolytic agents. It would flows logically to combine those agents herein into a fat-degradation promoting composition since they are known to be useful individually for promoting fat degradation. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of result effect parameters (e.g., amount of the actives) is obvious as being within the skill of the artisan. Based on the cited prior art, employing the fat-degradation promoting composition in a method of treating cellulite would have been reasonably expected to be useful since promoting fat degradation would decrease the local accumulation of fat and treating cellulite thereby, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ natural gum such as carageenan and gelling agents such as polyvinylpyrrolidine into the topical emulsion composition because these agents are known to be useful as gelling agents to increase the viscosity of the composition. Therefore, employing these gelling agents would have been reasonably expected to be useful to formulate a gelling emulsion composition, absent evidence to the contrary.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected

benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, only the example in pages 12-13 of the instant specification, with the data presented in the declaration by Dr. Pugliese filed May 10, 2002, has been considered. The examples merely demonstrate the effectiveness of the herein claimed composition in treating cellulite. This is seen to be an expected effect based on the cited prior art. No convincing and clear unexpected result is seen.

Response to the data presented in the declaration by Dr. Pugliese

Please see the discussion above.

Response to Arguments

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant's rebuttal arguments averring no motivation being provided by the cited prior art have been considered but are not found persuasive. All the herein

claimed active compounds are known to be useful as a fat-degradation promoting agent. It would flow logically from these prior art teachings to combine all the actives herein into one composition useful for the very same purpose. Moreover, employing such fat-degradation promoting composition to reduce the fat deposition under the skin, and treating cellulite thereby, would therefore be reasonably expected to be effective and useful in view of the prior art teachings of their uses individually, absent evidence to the contrary.

Applicant's rebuttal arguments averring Soudant et al.'s failure to teach the mechanism of action of caffeine and carnitine have been considered moot since the limitation is not recited in the claims. Argument directed towards unclaimed limitation is considered moot.

Applicant's arguments averring the cited prior art's failure to teach the actives herein being topically applied have been considered but are not found persuasive. The skilled of artisan would possess all conventional administration method of the active compounds such as oral administration. Absent showing the criticality of topical administration of the herein claimed composition, the selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
September 9, 2002

RT
RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200